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Irun R. Cohen

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EXAMINER

NOBLE, MARCIA STEPHENS

ART UNIT

PAPER NUMBER

1632

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,558	<b>Applicant(s)</b> COHEN ET AL.	
	<b>Examiner</b> MARCIA S. NOBLE	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-22, 24-32, 49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) 10, 12-22, 24-32, 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/2008</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-10, 12-22, 24-32, 49, and 50 are pending. Claims 1, 2, 6, 8, and 9 are amended and claims 11 and 23 are canceled by the amendment filed 12/21/2008.

### ***Election/Restrictions***

2. Claims 10, 12-22, 24-32, 49 and 50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/22/2008.

Claims 1-9 are under consideration.

### ***Withdrawn Rejections***

3. The rejection of claims 1, 3-6, and 9, under 35 U.S.C. 102(b) as being anticipated by Kokuho et al (Immunology and Cell Biology 75(5):515-518, 1997), as set forth in the Office Action, mailed 8/21/2008 (pp. 6-7), is withdrawn.

Applicant amended the claims to recite "human CD25" and Kokuko et al discloses pig CD25. Therefore, Kokuho et al no longer encompasses subject matter of the claimed invention and the rejection is withdrawn.

4. The rejection of claims 3 and 4, under 35 U.S.C. 102(b) as being anticipated by Cheng et al (Zhongguo yi xue ke xue yuan xue bao. Acta Academiae Medicinae Sinicae

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17(5);326-332, abstract; 1995), as set forth in the Office Action, mailed 8/21/2008 (pp. 8-9), is withdrawn.

Applicant amended the claims to remove the recitation, "homologs and fragments thereof". Therefore, claim 3 now requires the full nucleic acid sequence as set for in SEQ ID NO:1 and claim 4 now requires the full amino acid sequences of SEQ ID NOS:2-4. Since the abstract of Chen et al does not disclose the sequences, it is silent as to whether it corresponds to SEQ ID NOS: 1-4. Therefore, the rejection is withdrawn for claims 3 and 4. It is noted that Examiner is trying to obtain the full reference to assess if the full reference serves as prior art.

5. The rejection of claims 1-4 and 6-9, because the specification, while being enabling for a composition comprising a recombinant construct comprising an isolated nucleic acid sequence encoding an antigen selected from CD25, homologs and fragments thereof; the nucleic acid sequence being operably linked to one or more transcription control sequences, wherein said recombinant construct is an eukaryotic expression vector; and a pharmaceutically acceptable carrier, adjuvant, excipient, or diluent, does not reasonably provide enablement for a DNA vaccine; does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims, as set forth in the Office Action, mailed 8/21/2008, is withdrawn.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 5, as previously presented, is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a recombinant construct comprising an isolated nucleic acid sequence encoding an antigen selected from CD25, the nucleic acid sequence being operably linked to one or more transcription control sequences, wherein said recombinant construct is an eukaryotic expression vector, and a pharmaceutically acceptable carrier, adjuvant, excipient, or diluent, does not reasonably provide enablement for a naked DNA vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of

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working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

The instant claims are drawn to a DNA vaccine. According to Dictionary.com ([www.dictionary.reference.com/browse/vaccine](http://www.dictionary.reference.com/browse/vaccine)), a "vaccine" is defined as "any preparation used as a preventive inoculation to confer immunity against a specific disease" (see definition # 1).

The specification discloses that the purpose of the instant invention is to provide effective DNA vaccinations for T cell mediated autoimmune disease (p. 11, lines 4-5). The specification discloses that T cell lines generated by vaccination with peptide derived from CD25 were suggested to be involved in protection from experimentally-induced autoimmune encephalomyelitis (p. 2, lines 9-12). The specification teaches that CD25 DNA administration induced a low but significant IgG response to two CD25 peptides present in rats with adjuvant-induced arthritis (p. 26, Example 3, lines 24-26). The specification teaches that the administration of CD25 DNA induced a T cell proliferative response in drained lymph node cells in rats with adjuvant-induced arthritis (p. 27, lines 9-12).

However, the specification fails to demonstrate that the administration of the CD25 DNA vector results in the prevention or treatment of symptoms associated with an autoimmune disease. The specification fails to provide evidence to teach that the administration of the CD25 vector convey immunity against an autoimmune disease. Therefore, the specification fails to provide specific guidance to teach that the CD25

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expression vector of the instant invention serves as a vaccine because CD25 does not provide immunity to a disease.

Furthermore, the art suggests that the achieving a protective immune response from a DNA vaccine is unpredictable in the art. Van Drunden Little-Van den Hurk et al (Immuno Rev 199:113-125, 2004) teaches that no DNA vaccine have been approved for medicinal use because there inefficiency or lack of producing a protective immune response (p. 114, par bridging col 1 and 2).

In summary, the instant invention is not enabled for the full breadth of the claim to a DNA vaccine because the specification fails to provide specific guidance to demonstration that CD25 expression vector of the instant invention functions as a vaccine (i.e.- confers immunity to a disease). Furthermore, the art teaches that the induction of a protective immune response from a DNA vaccine is unpredictable. Therefore, because the specification fails to provide specific guidance to predictably produce a CD25 DNA vaccine capable of conferring immunity to a disease with a reasonable expectation of success and without undue experimentation, the instant claims are only enabled for composition comprising a recombinant construct comprising an isolated nucleic acid sequence encoding an CD 25 antigen; the nucleic acid sequence being operably linked to one or more transcription control sequences, wherein said recombinant construct is an eukaryotic expression vector; and a pharmaceutically acceptable carrier, adjuvant, excipient, or diluent.

Applicant's arguments filed 8/21/2008 have been fully considered but they are not persuasive.

First, the instant rejection is being maintained for claim 5 because it still encompasses a DNA vaccine. As previously discussed, the specification teaches an intended use of protective immunity against autoimmune disease and provides evidence of an immune response in adjuvant induce arthritis. However, the specification does not teach a protective immune response against adjuvant arthritis and the art teaches that achieving a protective immune response with DNA vaccines are unpredictable in the art, as taught by Van Drunden. Therefore, the instantly claimed naked DNA vaccine is not enabled for the intended use disclosed by the specification.

Applicant asserts that the specification provides specific guidance to demonstrate a therapeutic composition conferring immunity to disease. Applicant refers to example 10 which demonstrates that rats treated with DNA encoding CD25 reduced symptoms of adjuvant induced arthritis (par bridging p. 9 and 10 in the remarks). Applicant further refers to example 8 which teaches a shift from a Th1 cytokine profile to a TH2 cytokine profile demonstrating protective immunity. Applicant's arguments are not found persuasive. While these results suggest the elicitation of an immune response, they do not demonstrate a protective immune response because a protective immune response encompasses protection against developing arthritis. The treated rats of Examples 2 and 8 still develop arthritis. Therefore, the DNA treatment does not provide a protective immune response as encompassed by a DNA vaccination.

Therefore, because the claim 5 still encompasses a DNA vaccine and because the arguments provided by Applicant does not overcome the rejection of claim 5, the rejection is maintained for claim 5.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, and 5-7, as amended or previously presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al (Zhongguo yi xue ke xue yuan xue bao. Acta Academiae Medicinae Sinicae 17(5);326-332, abstract; 1995).

The structural components of the amended claims comprise a eukaryotic expression vector comprising a therapeutically effective amount of a nucleic acid sequence encoding a human CD25 operably linked to a transcriptional control sequence and a pharmaceutically acceptable carrier. The preamble of the amended claims recites that the composition is a therapeutic composition. However, if the structural components of the claimed invention are disclosed in the prior art, the limitations of the claims have been met regardless of whether the claimed vector is used as a therapeutic composition, DNA vaccine, or another use.

Cheng et al discloses a pRc/CMV eukaryotic expression vector encoding a fragment of the human IL-2 receptor alpha (abstract). The specification discloses that IL2-R alpha is CD25 (see page 4, line 12 of the specification). The amended claims

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recite "a therapeutically effective amount of a recombinant construct comprising an isolated nucleic acid sequence encoding an antigen, said antigen being human CD25". The breadth of "a therapeutically effective amount" encompasses an amount sufficient for expression of the construct by a treated cell. Cheng et al discloses that the expression vector was transfected and expressed in CHO cells (abstract). Therefore, this disclosure teaches a therapeutically effective amount of the construct, as claimed, because the treated CHO cells expressed the expression vector. The breadth of this recitation also encompasses an isolated nucleic acid sequence encoding enough of the human CD25 necessary to have the ability to serve as an antigen. Cheng et al discloses that the vector encodes a secretable form of CD25 comprising a deletion of the sequence encoding the cytoplasmic domain, transmembrane domain, and 5' untranslated region (abstract, lines 1-3). Therefore, Cheng et al discloses a CD25 with all of its functional domains present and enough of the CD25 necessary for it to serve as an antigen. Thus, overall, Cheng et al discloses the new limitation recited in claims 1, 5, and 7. Amended claim 2 now recites that the composition contains "a targeting carrier. Amended claim 6 specifies that is a liposome, micelles, emulsions, or cells. Cheng et al discloses that the in expression vector was transfected and expressed in CHO cells. Therefore, Cheng et al discloses the limitations of amended claims 2 and 6.

In conclusion, Cheng et al discloses the limitations of amended claims 1, 2, and 5-7. Therefore, the rejection of record is maintained.

Applicant's arguments filed 12/21/2008 have been fully considered but they are not persuasive. Applicant states that the claims have been amended to remove the recitation of "a homolog or fragments thereof". Applicant further asserts that Cheng et al discloses a fragment of the human IL-2R alpha nucleotide sequence and the claims no longer encompass a fragment. Therefore, Cheng et al does not disclose the claimed invention (p. 12, par 2 and 3 under "Cheng Reference"). This argument is not found persuasive because the claims do not limit the invention to a full length CD25 nucleic acid. The claims broadly claim "an isolated nucleic acid sequence encoding an antigen, said antigen being human CD25". Therefore, contrary to Applicant's assertion, the claims do still encompass a fragment, as long as said fragment encodes a sequence of the human CD25 capable of serving as an antigen. Cheng et al discloses a nucleic acid encoding a secretable form of the CD25 with biological activity and all of the functional domains of the full length CD25. Clearly, Cheng et al discloses a sequence that encodes a human CD25 capable of serving as an antigen. Therefore, Cheng et al discloses the limitations of the claims.

Applicant asserts that the amended claims require a therapeutically effective amount of the recombinant construct and Cheng et al does not teach a therapeutically effective amount. Applicant asserts that Cheng et al merely teaches a cell line expressing a soluble CD25. Applicant's arguments are not found persuasive for two different lines of reasoning. First, the instant claims are drawn to a product comprising a nucleic acid expression vector. The recitation of "a therapeutically effective amount" does not structurally change the present vector and at most suggests only effects the

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amount of the expression vector present in the composition. Therefore, with this line of reasoning "a therapeutically effective amount" has little to no patentable weight in consideration of the art because it does not affect the material structure of the claimed product. Second, the claims do not specify to whom or what the expression vector is therapeutic or in a therapeutic amount. Therefore, the breadth of the claims encompass, treating and altering the expression of a cell. Cheng et al discloses that the CHO cells expressed and secreted the CD25. Therefore, Cheng et al discloses a therapeutically effective amount of the expression vector was present in the CHO cell, because the treated CHO cells expressed the expression vector. Thus, with either line of reasoning disclosed above, Applicant's argument is not found persuasive.

Applicant asserts that CHO cells can not be would not be considered a carrier by an ordinary artisan for a therapeutic composition. Applicant's argument are not found persuasive. The structural limitations of the instant product are a construct comprising a nucleic acid encoding CD25 operably linked to a transcriptional control sequence and a pharmaceutically acceptable carrier, adjuvant, excipient, or diluent (see claim 1). Claim 2 specifies that composition also comprise a targeting carrier. Claim 6 species the targeting carrier is a cell, among others possibilities. The claims do not specify the structural limitations of the cell that is used as a carrier. Therefore, the breadth of the claims encompasses a cell comprising the claimed expression vector, which is taught by Cheng et al. It is noted that Cheng et al provides discloses the product as claimed with a different intended use. Even though, Cheng et al does not teach the intended use of a therapeutic DNA vaccine as claimed (see claim 5, which still recites, a DNA

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vaccine). Cheng et al teaches all the structural limitations of the product. Hence Cheng et al still anticipates the instant claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-9, as amended or previously presented, are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (Zhongguo yi xue ke xue yuan xue bao. Acta Academiae Medicinae Sinicae 17(5);326-332, abstract; 1995), in further view of NM\_00417 (NCBI Entrez Nucleotide. Hafler et al; <http://www.ncbi.nlm.nih.gov/entrez/viewer/fcgi?db=nucore&id=4557666>, see printout pages 1-5; of record), NP\_000408 (NCBI Entrez Protein. Hafler et al. <http://www.ncbi.nlm.nih.gov/entrez/viewer/fcgi?db=Protein&id=4557667>, see printout pages 1-4; of record), and Karin et al (US Pat No. 6,316,420 issue date: 12/3/2001; of record), as set forth in the Office Action, mailed 8/21/2008 (pp. 9-12).

Cheng et al teaches a pRc/CMV eukaryotic expression vector encoding a fragment of the human IL-2 receptor alpha (abstract). The specification discloses that IL2-R alpha is CD25 (see page 4, line 12 of the specification). This teaching of Cheng et al encompasses the limitations of claims 1, 2, 5, and 7. Claim 6 specifies that the

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composition comprises the structural component of a liposome, micelles, emulsions, or cells. Cheng et al teaches that the in expression vector was transfected and expressed in CHO cells (abstract). Therefore, Cheng et al teaches the limitations of claim 6.

Cheng et al also teaches that the establishment of rhlIL-2R alpha expressing cell lines is of importance in the detection and purification of IL-2 based on the ability of affinity binding between IL-2 and its recombinant receptor (abstract). Therefore, Cheng et al teach a motivation for producing expression vectors encoding CD25.

Cheng et al does not specifically teach that the nucleic acid encoding CD25 is the sequence of SEQ ID NO:1, as claimed in claim 3. Cheng et al also does not specifically teach that the amino acid encoded by the vector comprises the sequence of SEQ ID NO:2, as claimed in claims 4 and 8. However, the specification teaches that SEQ ID NO:1 corresponds to gi:4557666 and SEQ ID NO:2 corresponds to gi:4557667. NM\_000417 from NCBI entrez Nucleotide teaches a nucleic acid sequence corresponding to gi: 4557666 and teaches that this sequence was present in the prior art as early as 1990 (see p. 2 of the printout). NP\_000408 from NCBI entrez Protein teaches an amino acid sequence corresponding to gi: 4557667, and teaches that this sequence was present in the prior art as early as 1986 (see p. 2 of the printout). Therefore, at the time of the invention, NM\_000417 and NP\_000408 teach that SEQ ID NO:1 and SEQ ID NO:2 was established in the prior art.

Cheng et al does not specifically teach all of the carriers, such as liposomes, micelles, and emulsions, as claimed in claim 6. However, Karin et al teach that liposomes, micelles, and emulsions, can be employed as carriers to deliver DNA

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vaccine expression vectors (col 4, lines 18-20). Therefore, at the time of the invention, all the claimed carriers and their use for delivering expression vectors were established in the prior art, as taught by Karin et al.

Cheng et al also does not teach the transcriptional control sequences, RSV control sequences, retroviral LTR sequences, SV-40 control sequences, and beta-actin control sequences, as specified in claim 8. However, Karin et al teaches expression vectors used to deliver DNA vaccines (col 3, lines 62-67). Karin et al teaches suitable promoters which may be employed in expression vectors include retroviral LTR, the SV40 promoter, CMV promoter, and beta-actin promoter (col 4, lines 43-48). Therefore, at the time of the invention, all of the claim transcriptional control sequences and their use in expression vectors were established in the prior art, as taught by Karin et al.

Cheng et al also does not teach all eukaryotic expression vectors, pcDNA3, pZeoSV2, pSecTag2, pDisplay, pEF/myc/cyto, pCMV/myc/cyto, pCR3.1, pCI, pBK-RSV, pBK-CMV, and pTRES, as specified in claim 9. However, Karin et al teaches that the recombinant construct for the production of a DNA vaccine can be selected from the group consisting of pcDNA3, pcDNA3.1(+/-), pZeoSV2(+/-), pSecTag2, pDisplay, pEF/myc/cyto, pCMV/myc/cyto, pCR3.1, pCI, pBK-RSV, pBK-CMV, and pTRES (col 4, lines 53-58). Therefore, at the time of the invention, the eukaryotic expression vectors were established in the prior art, as taught by Karin et al.

Karin et al also teaches pharmaceutically acceptable carriers (col 4, lines 1-7).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to choose from a finite number of predictable CD25 sequences,

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as taught by NM\_000417 and NP\_000408, and a finite number of predicable carriers, transcriptional control sequences, and eukaryotic expression vectors as taught by Karin et al, with a reasonable expectation of successfully producing an eukaryotic expression vector variant of Cheng et al comprising a nucleic acid encoding a CD25 operably linked to a transcriptional control sequence and a pharmaceutically acceptable carrier.

Therefore, because the prior art of Cheng et al, NM\_000417 and NP\_000408, and Karin et al demonstrate that the components of the instantly claimed expression vector were established in art and predictably can be combined to produce the instantly claimed expression vector, the prior art of Cheng et al, NM\_000417 and NP\_000408, and Karin et al render the instant claims obvious over the prior art.

Applicant's arguments filed 12/21/2008 have been fully considered but they are not persuasive. Applicant asserts Chen et al is not directed to human therapy of any kind and thus provides no motivation or suggestion of the present invention (p. 14, lines 1-2 of remarks).

Applicant's argument is not found persuasive because the art does not need to teach the same intended use or motivation as those disclosed in the specification. The prior art only needs to teach a motivation of any sort to combine the prior art element and it need not be the same as that disclosed in the instant invention. As acknowledged by Applicant, Cheng et al teaches a cell line expressing soluble recombinant human IL-2Ralpha is of importance in the detection and purification of IL2 based on the ability of affinity binding between IL-2 and its recombinant receptor.

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Applicant further acknowledges that this is a motivation (p. 12, last par, lines 1-5 of remarks). Therefore, Cheng et al provides a motivation to substitute any IL-2Ralpha sequence, such as those taught by NM\_000417 and NP\_000408, into the vector of Cheng et al. While this may be a different motivation and intended use than that disclosed by the specification, it still provides a motivation to combine the prior art element to produce the claimed composition with the same structural composition. Therefore, contrary to Applicant's assertion, Cheng et al does provide motivation to combine the prior art elements.

Applicant asserts that CHO cell would not be used in a therapeutic composition to confer protective immunity against an autoimmune disease (p. 14, par 1, lines 1-3). This argument is not found persuasive because the claims are drawn to a product that does not require structural components necessary for treating and protecting against an autoimmune disease. Claim 6 specifies "cells" as a possible carrier. The claims do not specify any structural components that would distinguish "cells" from CHO cells. Therefore, CHO cells encompass the limitations of the claims.

Applicant states that the prior art of Van Drunden, as used in the enablement rejection, suggests that achieving a protective immune response from a composition intended as a DNA vaccine is unpredictable. Applicant therefore asserts that one of ordinary skill in the art would not have a reasonable expectation of success in using the CD25 expression vector of Cheng in producing a clinically effective DNA vaccine composition (p. 14, par 1, lines 4-8 of remarks).

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Applicant's argument is not found persuasive because the claims encompasses a product with the structural limitations of a nucleic acid encoding a human CD25 operably linked to a transcription control sequence in a eukaryotic expression vector. Cheng et al, NM\_000417, and NP\_000408 teaches these structural components for a different intended use. The claims no longer disclose the vector as a DNA vaccine. Therefore the vector does not need to be enabled for such a use. Cheng et al and the other secondary arts provide a different use of the composition, which is the express it as a recombinant protein in a cell, which they do successfully. Therefore, contrary to Applicant's assertion, an artisan of ordinary skill would have a reasonable expectation of successfully producing the claimed composition and using it to express a recombinant protein in a cell. Therefore, because the claimed product does not require that the product be used as a DNA vaccine and because the prior art does provide an enabled intended use and motivation to produce the claimed composition, Applicant's arguments are not found persuasive.

Applicant further traverses the combination of NM\_000417, NP\_000408, and Karin with Cheng et al on the grounds of unpredictability as discussed above. Applicant further states that Karin et al further demonstrates the unpredictabilities of DNA vaccines. Thus, an artisan would not have a reasonable expectation of successfully producing a DNA vaccine. As discussed above, the claims do not require the intended use of a DNA vaccine. Hence the claimed composition can be used in other ways, such as the express a recombinant CD25 in a cell, as disclosed by Cheng. Therefore, the art does enable the combination of the prior art to produce such an expression vector.

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Further, as previously stated in the rejection, Karin et al was not used for its teachings of DNA vaccines but rather to demonstrate that the various carrier of claim 6 and promoters of claim 7, and plasmids of claim 9 were established in the prior art and given the finite number of predictable possible carriers, promoters, and plasmids in the prior art, an artisan would arrive at the claimed composition with a reasonable expectation of success. Thus, Applicant's arguments are not found persuasive.

Overall, the instant rejection is maintained because the amended claims are still taught by the prior art and Applicant's arguments are not found persuasive in overcoming the rejection of record.

9. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/  
Primary Examiner, Art Unit 1632

Marcia S. Noble